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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/582,847

09/10/2008

Dror Seliktar

32156

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67801

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03/25/2010

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EXAMINER

EVERAGE, KEVIN D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

03/25/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/582,847	Applicant(s) SELIKTAR ET AL.	
	Examiner KEVIN EVERAGE	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 134, 138-142, 149-153, 158-165, 170-175 and 178-180 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 134, 138-142, 149-153, 158-165, 170-175 and 178-180 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendment filed November 25, 2009 is fully considered. Claims 1-133 were previously cancelled. Claims 135-137, 143-148, 154-157, 166-169 and 176-177 are now cancelled. Claims 178-180 are new. Claims 134, 138-142, 149-153, 158-165, 170-175 and 178-180 are currently pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 134, 138-142, 149-153, 158-165, 170-175 and 178-180 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tartaglia et al. (US 5,637,113) in view of Desai et al. (US 5,550,178).**

Tartaglia et al. ("Tartaglia") discloses a medical device comprising:

an expandable stent (20) covered by a polymer film (24) including cross-linked polyethylene glycol (PEG) (see column 2, lines 56-67);

wherein said stent is a balloon expandable stent (see column 4, lines 44-46);

wherein said polymer film further comprises a biologically derived polymer (see column 2, lines 56-67);

wherein said polymer film further comprises an anti-thrombogenic or anti-

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restenotic vascular re-healing drug (see column 1, lines 57-64);

wherein the rolled polymer film is unrolled in the lumen of a blood vessel thereby exposing the luminal wall of the vessel to a substance (see column 7, lines 18-22); and

wherein inserting the rolled polymer is effected using a catheter (see column 4, lines 44-46).

Tartaglia does not disclose the stent being self-expandable. However Tartaglia does disclose the stent being comprised of nickel-titanium alloy (nitinol; see column 5, lines 18-48), a known shape memory polymer. It would have been obvious to someone of ordinary skill in the art at the time of the invention to exploit the shape memory characteristics of the nitinol stent to make the stent self-expandable being that both nitinol and self expandable nitinol were very well known in the art.

Tartaglia does not disclose the polymer film comprising an alginate, the film comprising a radial swelling ration upon hydration of about 1. However Desai et al. ("Desai") discloses the use of alginate see column 5, lines 14-24) with biodegradable, cross-linked and polymerizable PEG to encapsulate biologics. It would have been obvious to someone of ordinary skill in the art at the time of the invention to use alginate in the stent covering film disclosed by Tartaglia to encapsulate the drug during delivery in light of Desai's disclosure. In regard to claim 172, Desai discloses drying the PEG film during the method of making (see column 9, lines 39-51). Modifying the Tartaglia film in the manner disclosed by Desai (to include alginate) would cause the chemical properties of the film to be at or near identical to the film disclosed in the present application. The radial swelling ratio upon hydration would this be about 1 (at or near

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identical to the claimed apparatus).

Regarding claims 178-180:

Tartaglia and Desai disclose the claimed invention except for the film's length being between 10-150 mm in length. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make a film between 10-150 mm to cover a stent of similar length, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

4. Applicant's arguments filed November 25, 2009 have been fully considered but they are not persuasive.

Applicant argues Desai teaches a gel-like substance and not a film. However the Examiner points to the abstract wherein Desai discloses using the methods and materials to encapsulate microcapsules. The capsule itself is the focus of the application and is itself an outer film of the capsule.

Applicant argues that the films disclosed by Tartaglia and Desai do not swell according to the claimed ratio. However being that Tartaglia and Desai disclose the claimed materials, and the materials do not disclose what composition of the materials is needed to achieve the desired swelling ratio, it would likewise follow that the same materials would have the same physical properties. Applicant discloses the optimal

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amount of CaCl_2 to create the desired material swelling property, but does not claim it.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN EVERAGE whose telephone number is (571)270-7485. The examiner can normally be reached on 9-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KEVIN EVERAGE
Examiner
Art Unit 3734

/K.E./

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734